IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327 MDL 2327**
THIS DOCUMENT RELATES TO: ***Linda Madding v. Ethicon, Inc., et al.*** **Case No.: 2:12-cv-02512**	**JOSEPH R. GOODWIN U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF
DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") hereby move for summary judgment on Plaintiff's substantive claims. There is no genuine dispute as to any material fact, and Ethicon is therefore entitled to judgment as a matter of law.

STATEMENT OF UNDISPUTED FACTS

1. On January 24, 2002, Plaintiff Linda Madding, ("Plaintiff") saw Dr. Julie Komarow, suffering with SUI and a large cystocele. Dr. Komarow counseled Plaintiff about Kegel exercises and referred Plaintiff to Dr. Sleeter for an examination and consultation. *See Defendant's Motion for Summary Judgment ("MSJ"),* ***Ex. 1***.

2. Tamara Sleeter, M.D., a Board certified obstetrician/gynecologist, took a course from Ethicon in Florida relating to treatment of SUI with the midurethral sling. TVT was the exclusive type of midurethral sling used in her practice. She kept up with the state of medical knowledge regarding the use of the midurethral sling and its risks through the medical literature, meetings with colleagues and other medical meetings. *MSJ,* ***Ex. 2****, Sleeter Dep. Tran. at 90:4 – 91:17 and 101:24-102:25.*

3. On February 28, 2002, Plaintiff presented to Dr. Sleeter with SUI, urine leakage, cystocele, rectocele, and severe uterine prolapse. *MSJ,* ***Ex. 3.***

4. On April 11, 2002, Plaintiff saw Dr. Sleeter for a pre-operative office visit regarding surgery for her cystocele, rectocele, and uterine prolapse, as well as SUI. *MSJ,* ***Ex. 4.*** Plaintiff's diagnosis was pelvic procidentia and SUI. Plaintiff leaked urine when she coughed and sneezed. Dr. Sleeter's plan was to perform a vaginal repair including an anterior and posterior repair, with sacrospinous fixation, and TVT placement. *MSJ,* ***Ex. 4 and 5.*** Plaintiff testified Dr. Sleeter did not show her any written information about the TVT product before her implant surgery. *MSJ,* ***Ex. 6,*** *Madding Dep. Tran. at 71:21-24.*

5. At the same visit, Dr. Sleeter discussed the risks and benefits of her proposed surgery. *MSJ, **Ex. 2** at 28:13-33:9 and 149:20-150:1.* The doctor's handwritten notes state she reviewed the benefits of reconstruction of pelvic support and TVT placement, the risks of bleeding, infection, harm to bladder/bowel, irritable bladder, and need for further surgery if her repair fails. *MSJ, **Ex. 4.*** Dr. Sleeter prepared a full-page, typed summary of the risks and benefits of anterior and posterior repair with sacrospinous fixation and TVT placement, which she specifically discussed with Plaintiff. *MSJ, **Ex. 2** at 28:13-24.* This record indicates Dr. Sleeter discussed the following risks with Mrs. Madding: (1) any operation has risks, (2) the most common problems in obstetrical and gynecological operations come from anesthetic complications, bleeding, infection, and trauma to internal organs, (3) complications may occur sometime after the surgery, (4) complications can be minor and annoying or major and life-treatening, (5) there is a possibility that over time the repair may fail and additional surgery may be necessary, (6) symptoms may be worse after this type of surgery, (7) a catheter may be needed for some time after the surgery, (8) leakage due to a fistula may occur, (9) the tape can erode through the structures of the bladder and urethra and vascular injuries and bowel injuries can occur, and (10) if the tape is too tight it may need to be partially or completely removed with return of incontinence is some cases. *MSJ, **Ex. 5.***

6. On April 29, 2002, Plaintiff was admitted to Valley Medical Center for surgery. According to the Operative Report, the preoperative diagnosis was "vaginal vault prolapse," and Dr. Sleeter performed an anterior-posterior repair, sacrospinous fixation, and placement of tension-free vaginal tape. *MSJ, **Ex. 7.***

7. Plaintiff testified she relied on Dr. Sleeter's opinion that use of the TVT product was appropriate to treat her symptoms and relied upon Dr. Sleeter's knowledge risks of the TVT. *MSJ, **Ex. 6** at 71:2-6 and 121:16-122:10.*

8. Dr. Sleeter testified that at the time she implanted the TVT in Plaintiff the use of TVT for the surgical treatment of SUI had become the standard of care. *MSJ, **Ex. 2** at 98:3-10.*

9. On April 30, 2002, the day after the surgery and while Plaintiff was still in the hospital, Plaintiff complained she could not void and "has tried everything." Her abdomen was distended and she was noted to be very uncomfortable. The nurse catheterized Plaintiff and immediately obtained 1000 cc. of urine and another 500 cc. of urine later. Plaintiff was discharged home with a Foley catheter in place and a leg bag. *MSJ, **Ex. 8**, and **Ex. 2** at 130:2-25.*

10. Plaintiff alleges that she first experienced symptoms related to her mesh a week after her surgery (in 2002). *MSJ, **Ex. 9,** Madding Plaintiff Fact Sheet, ("PFS") § II.6.b.*

11. During May 2002, Plaintiff presented at Dr. Sleeter's office at least three times complaining of inability to void, then urinary frequency and urgency and spasms. She needed a Foley catheter following surgery for over two weeks, and thereafter continued to self-catheterize as needed. *MSJ, **Ex. 10, Ex. 11**, **Ex.12**.*

12. Plaintiff's symptoms and the need to periodically self-catheterize continued through at least August 2002. *MSJ, **Ex. 13, Ex. 14, Ex. 15.***

13. In early 2003, Plaintiff continued to report having trouble urinating without good flow. She reported urine dribbles, slow to empty, increased urgency, and still self-catheterizing at times. But, she was not leaking. A pelvic exam showed a recurrent anterior second degree cystocele with a palpable anterior defect. Dr. Sleeter noted the TVT was holding nicely. A urodynamic study was ordered and urine culture was sent. *MSJ, **Ex. 16**.*

14. On February 19, 2003, Plaintiff filled out a Bladder Health Questionnaire for Dr. Sleeter's office. She wrote she was urinating six to ten times a day, getting up two to three times a night to urinate, usually had a strong urgency to urinate, could not easily postpone emptying her bladder, had pain when her bladder was full, and could not completely empty her bladder. In

her own handwriting, Plaintiff answered the question asking how long ago her bladder problems began by indicating "May 2002." *MSJ, **Ex. 17***.

15. On April 17, 2003, Plaintiff complained of urgency, not emptying bladder, with a "dribbly, slow stream." She told Dr. Sleeter her urinary symptoms were much worse than prior to surgery. *MSJ, **Ex. 18***.

16. Shortly before November 10, 2013, Plaintiff complained of "not peeing right," had frequent urination, urinary hesitancy, and was occasionally self-catheterizing. She stated she was not happy with Sleeter. *MSJ, **Ex. 19***. On November 10, 2003, Plaintiff saw Dr. Hunter McKay, a urologist, for the first time. Plaintiff's symptoms were slow and intermittent stream, frequency, and difficulty initiating urine flow. She indicated she was celibate and dyspareunia was not an issue. Dr. McKay working diagnosis was urethral syndrome versus de novo detrusor instability. His plan was to prescribe Macrodantin for 6-12 weeks and order more diagnostic studies if she improved. *MSJ, **Ex. 20***.

17. On October 4, 2004, Dr. McKay performed additional diagnostic studies. He diagnosed "OAB retention and ? urethral syndrome. Mild PR." *MSJ, **Ex. 21***. By February 14, 2005, Dr. McKay had concluded it was likely there was an obstruction of the urethra that was causing the retention, and that that obstruction was due to the presence of the mesh. *MSJ, **Ex. 22**, McKay Dep. Tran. at 100:6-101:8.* Dr. McKay recommended a "takedown" of the TVT. His records show he told Plaintiff the TVT "takedown" may be helpful for her obstructive urinary symptoms and findings. *MSJ, **Ex. 23***.

18. Even though Dr. McKay does not have an independent recollection of his communication with Plaintiff regarding the cause her retention, based upon his custom and practice, and given Plaintiff's symptoms and his conclusion following the failure of conservative treatment that some kind of mechanical obstruction was causing Plaintiff's urinary retention, he

testified he would have had a "frank discussion [with Plaintiff] about the likely diagnosis which is obstruction and the likely culprit being the previous TVT." *MSJ, **Ex. 22** at 101:2-102:11.*

19. On March 1, 2005, Dr. McKay performed the "takedown" revision of the TVT at Valley Medical Center. In his Operative Report, he noted the indications for surgery were TVT in April 2002 and the patient had been troubled by urinary retention, slow and intermittent stream, and overactive bladder difficulties. In his description of the procedure, Dr. McKay noted the "band" of obstructing polypropylene was identified by palpation with the aid of a 24 French Foley catheter per urethra. He removed several sections of the TVT and no tape remained under the urethra. There were no apparent surgical complications. *MSJ, **Ex. 24**.*

20. At surgery, Dr. McKay did not note any evidence that the TVT was infected, degraded, curled, roped, or frayed. He did not observe any abnormalities in the TVT at all. He testified he would have noted any of these abnormalities in his operative report, if he had observed such abnormality. *MSJ, **Ex. 22** at 87:2-89:10.*

21. Dr. McKay testified it was his assumption before the TVT "takedown" surgery that Plaintiff's symptoms were caused by an obstructive uropathy and she had a good chance of improving if he removed the "obstructing TVT." He testified the proof the TVT was causing the obstruction was Plaintiff's clinical improvement after the surgery. *MSJ, **Ex. 22** at 21:25-22:15 and 32:19-23.*

22. On April 6, 2005, Dr. McKay saw Plaintiff for the last time, and reported that her symptoms were quite a bit improved following the "takedown" of the TVT. All symptoms were better and the tests showed no residual urine. She was told to return as needed. *MSJ, **Ex. 25.***

23. Dr. McKay testified "In the case we are talking about, Linda Madding, I do not believe the TVT is defective." *MSJ, **Ex. 22** at 23:2-5.*

24. Plaintiff admitted at deposition she thought removing the TVT may stop the incomplete bladder emptying she had experienced since the implant. *MSJ, **Ex. 6** at 93:3-5.*

25. Plaintiff testified after the surgery by Dr. McKay the inability to urinate had gotten better. *MSJ, **Ex. 6** at 100:23-25.*

26. When asked what injuries she suffered as a result of the mesh, she indicated she had the mesh done in April 2002 and dealt with it for almost three solid years. *MSJ, **Ex. 6** at 104:22-105:16.*

27. Plaintiff admitted she has not suffered any injuries since March 2005 that she claims are related to the TVT product. *MSJ, **Ex. 6** at 105:13-16.*

28. On July 2, 2012, Plaintiff filed this product liability action in the Southern District of West Virginia. *See* Complaint, 7/2/12, Dkt. 1 ("Compl."). She filed an Amended Complaint on December 25, 2012. *See* Amended Complaint, 12/25/12, Dkt. 12 ("Amen. Compl."). On February 9, 2016, Plaintiff filed a Second Amended Complaint. *See* Second Amended Complaint, 2/9/16, Dkt. 24 ("Sec. Amen. Compl.").

ARGUMENT

Summary judgment is proper where there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(a). Pursuant to the well-established summary judgment standard, *see, e.g.*, *Lowe v. Matheney*, No. 2:13-CV-22416, 2015 WL 5795870, at *2 (S.D.W. Va. Sept. 30, 2015), Ethicon is entitled to summary judgment, and Plaintiff's Complaint should be dismissed with prejudice.

I. WASHINGTON SUBSTANTIVE LAW GOVERNS PLAINTIFF'S CLAIMS.

This Court has ruled that for cases filed directly in the MDL, "the choice of law that applies is the place where the plaintiff was implanted with the product." *Belanger v. Ethicon, Inc.*, No. 2:13-cv-12036, 2014 WL 346717, at *7 (S.D. W. Va. Jan. 30, 2014); *see also Lewis v.*

Ethicon, No. 2:12-cv-4301, 2014 WL 186869, at *2 (S.D.W. Va. Jan. 15, 2014) ("In cases based on diversity jurisdiction, the choice-of-law rules to be used are those of the states where the actions were originally filed.").[1] Here, Plaintiff's TVT implant surgery was performed in Washington, and thus its choice-of-law rules apply. *MSJ, **Ex. 9**, PFS § II.1*. Washington applies the most significant relationship test to determine choice of law. *Tilden-Coil Constructors, Inc. v. Landmark Am. Ins. Co.*, 721 F. Supp. 2d 1007, 1016 (W.D. Wash. 2010).[2] It is presumed that the law of the state where the injury occurred applies unless another state has a more significant relationship. *See* Restatement (Second) of Conflict of Laws § 146.

Plaintiff's injuries, if any, occurred in Washington, and there is nothing to overcome the presumption in favor of the law of the place of injury. Plaintiff resides in Washington. She lived in Washington at the time the TVT was implanted and revised. Her implant and revision procedures were performed in Washington, and Plaintiff's implanting physician (the learned intermediary) practiced medicine in Washington. *MSJ, **Ex. 9**, PFS §§ I.4, II.1, II.5.a, III.6.* Washington substantive law thus applies to Plaintiff's compensatory damage claims.[3]

II. PLAINTIFF'S PRODUCT LIABILITY CLAIMS ARE TIME-BARRED.

The Washington Product Liability Act ("WPLA") creates a single "product liability claim" that consolidates common law product liability theories into one. *See* Wash. Rev. Code §

[1] Plaintiff's complaint was filed in the MDL, in the Southern District of West Virginia, on July 2, 2012.

[2] The most significant relationship test considers: "(a) the place where the injury occurred; (b) the place where the conduct causing the injury occurred; (c) the domicile, residence, nationality, place of incorporation, and place of business of the parties; and (d) the place where the relationship, if any, between the parties is centered." *Tilden-Coil Constructors, Inc.*, 721 F. Supp. 2d at 1016 (citing Restatement (Second) of Conflict of Laws § 145).

[3] New Jersey law applies to Plaintiff's punitive damages claim.

7.72.010[4]; *see also Hue v. Farmboy Spray Co.*, 127 Wash. 2d 67, 75 n.10 (1995) ("the [W]PLA creates a single cause of action for product-related harm with specified statutory requirements for proof."); *Wash. Water Power Co. v. Graybar Elec. Co.*, 112 Wash. 2d 847, 854, *amended sub nom.* 779 P.2d 697 (Wash. 1989) (finding WPLA preempts common law product liability claims). Under Washington law, a product liability claim must be brought within "three years from the time the claimant discovered or in the exercise of due diligence should have discovered the harm and its cause." Wash. Rev. Code § 7.72.060(3). The discovery rule is satisfied when the claimant discovered or should have discovered "a factual causal relationship of the product to the harm." *N. Coast Air Servs., Ltd. v. Grumman Corp.*, 111 Wash. 2d 315, 319 (1988).

Applying Washington law, in cases with nearly identical facts, federal courts have held the entire action time-barred. In *In re Mentor Corp.*, the plaintiff, a Washington resident, was implanted with ObTape in 2004. No. 4:08-MD-2004 (CDL), 2015 WL 6134398, at *1 (M.D. Ga. Oct. 19, 2015). In 2005, after she reported urethral pain, the plaintiff and her implanting physician discussed sling revision surgery, but plaintiff canceled the procedure. *Id.* In 2007, the plaintiff visited her primary care physician and complained of vaginal pain, which she attributed to ObTape, and her doctor recommended a gynecological consult to consider sling removal. *Id.* In June 2010, she complained of possible urethral bleeding and foul-smelling discharge, which she again attributed to the ObTape, and her physician diagnosed mesh erosion. *Id.* Thereafter,

[4] "'Product liability claim' includes any claim or action brought for harm caused by the manufacture, production, making, construction, fabrication, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging, storage or labeling of the relevant product. It includes, but is not limited to, any claim or action previously based on: Strict liability in tort; negligence; breach of express or implied warranty; breach of, or failure to, discharge a duty to warn or instruct, whether negligent or innocent; misrepresentation, concealment, or nondisclosure, whether negligent or innocent; or other claim or action previously based on any other substantive legal theory except fraud, intentionally caused harm or a claim or action under the consumer protection act …."

the plaintiff underwent two surgeries to remove exposed mesh, the first in September 2010 and the second in March 2011. *Id.* She then filed her complaint on July 12, 2013. *Id.* at *2.

The district court dismissed the case holding the statute of limitations began to run by 2007. *Id.* at *2. The court stated, "[B]y 2007 at the latest, a reasonable person in [the plaintiff's] situation would have suspected that her injuries were caused by the ObTape and would have been able to begin an investigation to determine whether those injuries were caused by a problem with ObTape, a problem with the implantation surgery, or some other problem." *Id.* The court further emphasized, "[The plaintiff] did not show that the facts constituting her claims against [the defendant] could not have been discovered through the exercise of due diligence before July 12, 2010." *Id.*

The circumstances in this case are more compelling for dismissal than those in *In re Mentor*. The TVT was implanted on April 29, 2002. The next day, Plaintiff experienced urinary retention, a risk of the TVT which Dr. Sleeter specifically warned could occur. Plaintiff continued to experience problems with urgency, frequency, retention, inability to empty, dribbling, and slow stream from the day after her TVT surgery until Dr. McKay's revision of the TVT on March 1, 2005.

Soon after the implant surgery, plaintiff began experiencing difficulty urinating, which she had not experienced prior to the implant surgery. *MSJ, **Ex. 6** at 80:24 - 81:6.* Plaintiff alleges she first experienced symptoms related to TVT on May 3, 2002 – **less than a week after the implant.** *MSJ, **Ex. 9**, PFS § II.6.b.* In February 2003, Plaintiff, in her own handwriting, answered the question asking how long ago her bladder problems with, "May 2002." *MSJ, **Ex. 17**.*

On March 1, 2005, Dr. McKay revised Plaintiff's TVT and removed all TVT from under her urethra. *MSJ, **Ex. 24**.* Dr. McKay thought the TVT was obstructing the urethra. *MSJ, **Ex. 22***

at 100:6-101:8. Prior to surgery, Dr. McKay told Plaintiff the "takedown" of the TVT may be helpful with her obstructive symptoms. *MSJ,* ***Ex. 23.***

Plaintiff admits she thought removing the TVT may stop the incomplete bladder emptying she had experienced since the implant. *MSJ,* ***Ex. 6*** *at 93:3-5.* Dr. McKay testified, based upon his custom and practice in 2005, he probably had a "frank discussion [with Plaintiff] about the likely diagnosis which is obstruction and the likely culprit being the previous TVT." *MSJ,* ***Ex. 22*** *at 101:2-102:11.*

A reasonable person in the plaintiff's situation would have suspected that her urinary retention and accompanying symptoms were related to the TVT product, **no later than March 2005** and would have been able to begin an investigation to determine whether those injuries were caused by a problem with the TVT, a problem with the implantation surgery, or some other problem. Plaintiff thought that removing the TVT may stop her bladder problems; but, she did not conduct any investigation to determine or confirm that her injuries were caused by TVT, even after it was removed and **most of her symptoms subsided**. Further, Plaintiff visited her doctors at least thirteen times before the revision surgery by Dr. McKay, with consistent problems related to retention, urgency, frequency, difficulty emptying her bladder and slow stream. After Dr. McKay incised the TVT and removed portions of it, almost all of Plaintiff's symptoms subsided. Plaintiff has not seen a doctor for urinary incontinence since Dr. McKay's March 2005 surgery. *MSJ,* ***Ex. 6*** *at 100:4-8.* She cannot show that the facts constituting her claims could not have been discovered at least by July 2009.

Plaintiff's claims are time-barred by Washington's three-year statute of limitation.[5] By **March 2005** – at the latest – Plaintiff discovered the harm and its cause, and she has admitted

[5] *See also Oliver v. Boston Sci. Corp.*, No. 2:13-CV-01736, 2015 WL 5838506, at *3 (S.D.W. Va. Oct. 5, 2015) (Florida law) (granting summary judgment when, "[i]n her deposition, [plaintiff] admitted that within a few weeks of her Obtryx implantation surgery, she told Dr. Jain,

this. Yet, Plaintiff waited more than **seven years** after her revision surgery to file her product liability claim, well past the three year limitation. Plaintiff's Complaint should be dismissed as her claims are time barred.

III. PLAINTIFF'S FAILURE-TO-WARN CLAIMS – INCLUDING THE STRICT LIABILITY, NEGLIGENCE, WARRANTY AND FRAUD-BASED WARNING CLAIMS (COUNTS I, III, VII, IX, X, XI, XII, XIII AND XIV) – ARE BARRED BY THE LEARNED INTERMEDIARY DEFENSE AND SHOULD BE DISMISSED.

Washington courts apply the learned intermediary doctrine to warning claims arising from the use of prescription medical devices. *See Terhune v. A. H. Robins Co.*, 90 Wash. 2d 9, 17 (1978); *see also Wash. State Physicians Ins. Exch. & Ass'n v. Fisons Corp.*, 122 Wash. 2d 299, 313 (1993). Under the doctrine, a manufacturer has a duty to warn only the prescribing physician, **not the plaintiff**. *See Terhune*, 90 Wash. 2d at 14. Furthermore, the physician has a "duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and to exercise an independent judgment." *Id.* In turn, "[t]he patient is expected to and, it can be presumed, does place primary reliance upon that judgment." *Id.* As a Washington appellate court recently explained, "[t]he patient places primary reliance on the physician's informed judgment, rather than whatever warnings the *manufacturer* may have included. Therefore, the physician is in a superior position to warn the patient and the courts should not interfere with the physician-patient relationship." *Taylor v. Intuitive Surgical, Inc.*, 188 Wash. App. 776, 788 (2015), *petition for review granted*, 184 Wash. 2d 1033 (2016) (internal quotations and citations omitted).

Notably, warnings of general and serious risk of injury are adequate; manufacturers need not inform of "every possible injury that could occur or of the mechanism that would cause

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her implanting physician, that 'I think it's the sling that's causing these problems.'"); *Smothers v. Boston Scientific*, No. 2:12-CV-4078, 2014 WL 3495977, at *4 (S.D. W. Va. July 11, 2014) (Massachusetts law) (granting summary judgment where "[i]t is clear from her testimony that the plaintiff was on notice that she had been harmed, and that her harm was attributable to the Obtryx sling as early as three weeks after implantation.").

injury." *Anderson v. Weslo, Inc.*, 79 Wash. App. 829, 840 (1995). Indeed, FDA device regulations explicitly provide that information commonly known to medical device users need not be included in a device's labeling. 21 C.F.R. § 801.109(c). A plaintiff must establish proximate cause, both cause in fact and legal causation. *Anderson,* 79 Wash. App. at 838.

The gravamen of Plaintiff's strict liability failure-to-warn and related warning claims is that Ethicon failed to warn about certain risks of TVT. *See* Sec. Am. Compl., ¶¶ 35-38.

A. Any Failure to Warn Was Not the Cause of Plaintiff's Alleged Injuries Because Dr. Sleeter Knew of the Risks.

A manufacturer cannot "fail" to warn about a risk when the physician is already aware of it. *See Wash. State Physicians Ins. Exch.*, 122 Wash. 2d at 315 ("it is generally true that a drug manufacturer's failure to warn a prescribing physician cannot be the proximate cause of the patient's injury if the physician was already aware of the risk involved in the use of the drug").

Prior to Plaintiff's TVT implant surgery, Dr. Sleeter was aware of the material risks associated with TVT. Specifically, Dr. Sleeter testified that she was aware that mesh placement surgeries are associated with risks of urinary frequency, urgency, dysuria or retention, and obstruction. *MSJ, **Ex. 2** at 90:4–91:17 and 101:24-102:25.* She testified she was aware of numerous risks for non-mesh SUI surgery and mesh SUI surgery before she implanted the TVT in Plaintiff. *MSJ, **Ex. 26 and 27,*** and ***Ex. 2*** *at* 103:17-106:21. Dr. Sleeter's April 11, 2002 record confirms that she reviewed the risks of the implantation and prepared a full page description of a summary of the risks and benefits of the surgery, which she discussed with Plaintiff. *MSJ, **Ex. 4 and Ex. 5,** and **Ex. 2** at 28:13-33:9 and 149:20-150:1.* Plaintiff relied on Dr. Sleeter's knowledge of the TVT. *MSJ*, ***Ex. 6** at 71:2-6.*

Because Dr. Sleeter was aware of these risks, Plaintiff cannot satisfy her burden of proving that an alleged failure to warn was a cause of her injuries.

B. Any Failure to Warn Was Not the Cause of Plaintiff's Alleged Injuries Because Different Warnings Would Not Have Changed Dr. Sleeter's Decision to Use TVT.

"The patient places primary reliance on the physician's informed judgment, rather than whatever warnings the *manufacturer* may have included." *Taylor*, 188 Wash. App. at 788. Under the circumstances, there can be no causal connection if different warnings would not have altered Dr. Sleeter's decision to use TVT. Dr. Sleeter testified that when she implanted TVT in Plaintiff it was the standard of care for the surgical treatment of SUI. *MSJ, **Ex. 2** at 98:3-10*. And significantly, Dr. Sleeter testified that if the 2002 IFU had warned of the risks included in the 2016 IFU (as proposed by Plaintiff's counsel), she still would have recommended TVT for Plaintiff in this case. *MSJ, **Ex. 2** at 122:4-13*. Different warnings would not have altered Dr. Sleeter's decision to recommend TVT for Plaintiff's SUI.

Plaintiff cannot establish that any alleged failure to warn was the cause of her injuries, and Plaintiff's failure-to-warn claims should be dismissed. [6]

IV. PLAINTIFF CANNOT ESTABLISH A DESIGN DEFECT UNDER THE RISK-UTILITY TEST OR CONSUMER EXPECTATIONS TEST, AND THUS PLAINTIFF'S STRICT LIABILITY DESIGN DEFECT AND DEFECTIVE PRODUCT (COUNTS V AND IV) CLAIMS FAIL AS A MATTER OF LAW.

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[6] The Washington Supreme Court has held that comment *k* of the Restatement (Second) of Torts section 402A, applies categorically to all prescription medical products because they are all "unavoidably unsafe." *See Terhune*, 90 Wash. 2d at 14; *Young for Young v. Key Pharm., Inc.*, 130 Wash. 2d 160, 170 (1996). Under comment *k* jurisprudence, however, the question of whether a prescription product manufacturer adequately warned a physician "raises an issue of negligence, not strict liability." *See Young*, 130 Wash. 2d at 169; *Estate of LaMontagne v. Bristol-Myers Squibb*, 127 Wash. App. 335, 343 (2005). A "warning for a prescription [product] may be adequate as a matter of law if it provides specific and detailed information about the risks." *Estate of LaMontagne*, 127 Wash. App. at 352. And, importantly, if "no matter how many warnings are given, or how detailed they are, it is simply impossible completely to prevent [product] injuries," summary judgment is appropriate. *Anderson*, 79 Wash. App. at 840. Here in the applicable TVT IFU, Ethicon warned that "overcorrection i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction." *MSJ, **Ex. 28,*** 2002 Gynecare TVT IFU, at ETH.MESH.05225383. Because Ethicon provided specific information about the specific risk experienced by Plaintiff, the TVT warnings were adequate as a matter of law.

Under the Washington Products Liability Act ("WPLA"), a plaintiff may establish a strict liability design defect under either the consumer expectations test or the risk-utility test. *Soproni v. Polygon Apartment Partners*, 137 Wash. 2d 319, 326 (1999). Plaintiff cannot meet her burden under either test.

Under the "consumer expectations" test, the plaintiff must show that the product was "unsafe to an extent beyond that which would be contemplated by the ordinary consumer." *Soproni*, 137 Wash. 2d at 327. "Under Washington law, the 'consumer' of a prescription-only medical device such as this is the physician, not the patient in whom it is installed…." *Adams v. Synthes Spine Co., LP.*, 298 F.3d 1114, 1117 (9th Cir. 2002). Pursuant to the risk-utility test, a plaintiff must show that "the likelihood that the product would cause the plaintiff's harm …, and the seriousness of those harms, outweighed the manufacturer's burden to design a product that would have prevented those harms." *Id.* (citing *Falk v. Keene Corp.*, 113 Wash. 2d 645, 654 (1989)). This test also considers any adverse effects that "a practical, feasible alternative would have on the product's usefulness." *Id.* A showing of a feasible alternative design is required under the risk utility test and is relevant under the consumer expectation test. Wash. Rev. Code § 7.72.030(1)(a); *Soproni*, 137 Wash. 2d at 326-27. Plaintiff bears the burden of establishing a feasible alternative design. *See Falk*, 113 Wash. 2d at 660 n.6.

Here, Plaintiff cannot meet her burden of proof under either test. Under the consumer expectations test, Plaintiff cannot establish that the product was unsafe beyond that which the "consumer" – Dr. Sleeter -- contemplated because each and every risk that Plaintiff experienced was known to Dr. Sleeter and was included in the informed consent discussion Plaintiff had with Dr. Sleeter. *MSJ,* ***Ex. 2*** *at 28:13-33:9, 103:17-106:21, and 149:20-150:1; and* ***Ex. 4, Ex. 5, Ex. 26,*** *and* ***Ex. 27****.*

Moreover, Plaintiff has presented no evidence that a feasible alternative design existed at the time TVT was brought to market, therefore failing to satisfy either test. Notably, evidence of alternative surgical procedures for the treatment of SUI is irrelevant to the existence of an alternative design.[7] *See, e.g.*, *McCarthy v. Danek Med., Inc.*, 65 F. Supp. 2d 410, 412 (E.D. La. 1999) ("[P]laintiff's experts have not offered or contended that alternative designs existed … at the time of surgery. Rather, plaintiffs and their experts have confused the existence of alternative methods with alternative designs."); *see also Theriot v. Danek Medical, Inc.*, 1997 U.S. Dist. LEXIS 22879, at *7-8 (E.D. La. Dec. 5, 1997), *aff'd*, 168 F.3d 253, 256 (5th Cir. 1999) (granting summary judgment on design defect claim where plaintiff submitted evidence of surgical alternatives instead of an alternative design); *Schmidt v. C.R. Bard, Inc*., 2013 U.S. Dist. LEXIS 101963, at *6 (D. Nev. July 22, 2013) (Nevada law) ("[N]on-mesh repair is not an alternative design and does not meet Plaintiff's burden to support [a design defect claim].").

Midurethral slings are the most studied SUI treatment in history, yet Plaintiff can cite no comparative study that demonstrates any clinical difference between laser-cut and machine-cut mesh. To the contrary, the pattern of complications did not change in 2007 when Ethicon introduced laser-cut TVT. *MSJ, **Ex. 29**, Expert Report of C. Matthews, M.D., at 22.*

The only "alternative design" Plaintiff offers is an opinion by Dr. Bruce Rosenzweig that a larger-pore mesh like Ultrapro[8] may be a safer alternative design. Dr. Rosenzweig cannot even opine that Ultrapro has an "acceptable" risk-benefit profile such that it can be safely used. *MSJ, **Ex. 30**, Rosenzweig 7/13/15 Dep. at 174:8-17.*

Further, the FDA refused to clear the lighter mesh for use for incontinence in 2011. *MSJ,*

[7] To the extent plaintiff's expert, Dr. Bruce Rosenzweig, opines an autologous sling procedure was available, this is an alternative surgery and not an alternative mid-urethral sling.

[8] Ethicon makes a lighter weight and larger pore hernia mesh, but does not use it for stress urinary incontinence.

***Ex. 31**, Colin M. Pollard's letter to Ethicon, ETH.MESH.00345111-00345118.* Thus, Plaintiff's claims for strict liability design defect and defective product[9] should be dismissed.

V. BECAUSE PLAINTIFF FAILS TO OFFER EVIDENCE THAT TVT DEVIATED FROM ETHICON'S SPECIFICATIONS, PLAINTIFF'S MANUFACTURING DEFECT CLAIM (COUNT II) SHOULD BE DISMISSED.

The WPLA provides that "[a] product manufacturer is subject to strict liability to a claimant if the claimant's harm was proximately caused by the fact that the product was not reasonably safe in construction." Wash. Rev. Code § 7.72.030(2). It follows that "[a] product is not reasonably safe in construction if, when the product left the control of the manufacturer, the product deviated in some material way from the design specifications." *Id.* at § 7.72.030(2)(a); *see, e.g.*, *Frye v. Biro Mfg. Co.*, No. C10-0192-JCC, 2011 WL 6013775, at *3 (W.D. Wash. Dec. 2, 2011) (providing as examples that the "deviation can be from a physical flaw or from incorrect assembly"). Here, there is no evidence that the TVT implanted in Plaintiff deviated from design specifications when it left Ethicon's control.

VI. PLAINTIFF'S NEGLIGENCE CLAIMS – NEGLIGENCE (COUNT I), NEGLIGENT MISREPRESENTATION (COUNT IX), NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS (COUNT X), AND GROSS NEGLIGENCE (COUNT XIV) – FAIL UNDER WASHINGTON LAW.

As noted, Plaintiff's negligence claims should be dismissed as duplicative of Plaintiff's failure-to-warn claim. Moreover, the WPLA preempts common law and governs all claims for product-related harm in Washington. *See* Wash. Rev. Code § 7.72.010(4) ("[under the WPLA,] '[p]roduct liability claim' includes any claim … for harm caused by the manufacture, production, making, construction, fabrication, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging, storage or labeling of the relevant product"); *see also Wash. State Physicians Ins. Exch.*, 122 Wash. 2d at 323 ("the [W]PLA preempts traditional

[9] A search of Washington law does not reveal a cause of action for "defective product," but to the extent this claim seeks to establish some variation of a design defect claim under the WPLA, it fails as a matter of law.

common law remedies for product-related harms").[10] Plaintiff cannot avoid the statutory scheme by asserting her product liability cause of action under a theory of negligence.

Plaintiff's claims for negligence, negligent misrepresentation, negligent infliction of emotional distress, and gross negligence should therefore be dismissed.

VII. PLAINTIFF FAILS TO SATISFY THE REQUIREMENTS OF COMMON LAW FRAUD (COUNT VI), FRAUDULENT CONCEALMENT (COUNT VII), AND CONSTRUCTIVE FRAUD (COUNT VIII), AND ACCORDINGLY, THESE CLAIMS SHOULD BE DISMISSED.

As noted, Plaintiff's fraud, fraudulent concealment, and constructive fraud[11] claims should be dismissed as duplicative of Plaintiff's failure-to-warn claim. In addition, the WPLA preempts common law claims for misrepresentation, concealment, and nondisclosure, whether negligent or innocent. *See* Wash. Rev. Code § 7.72.010(4) ("[under the WPLA,] '[p]roduct liability claim' includes any claim … for harm caused by misrepresentation, concealment, or nondisclosure, whether negligent or innocent"); *see also Wash. State Physicians Ins. Exch.*, 122 Wash. 2d 299, 323 (1993) ("the [W]PLA preempts traditional common law remedies for product-related harms"). Plaintiff cannot avoid the statutory scheme by re-labeling her claims.

Additionally, a claim for common law fraud may be maintained only upon a showing of "intentionally caused harm." *Id.* There are nine elements required to establish a claim for fraud in Washington: (1) representation of an existing fact; (2) materiality; (3) falsity; (4) the

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[10] *See also Laisure-Radke v. Par Pharm., Inc.*, 426 F. Supp. 2d 1163, 1168 (W.D. Wash. 2006) (dismissing as a matter of law plaintiff's claims for negligent failure to warn, negligent failure to test, negligent misrepresentation and overpromotion, and negligent marketing, among others); *id.* ("[T]he WPLA preempts traditional common law remedies for product-related harms. Such [a] claim previously based on negligence is within the definition of a product liability claim.") (internal quotations and citation omitted); *Wash. Water Power Co. v. Graybar Elec. Co.*, 112 Wash. 2d 847, 853 (1989) ("the WPLA means nothing if it does not preempt common law product liability remedies"); *cf. Bylsma v. Burger King Corp.*, 176 Wash. 2d 555, 560 (2013) (permitting recovery for emotional distress under the WPLA because the claims were based on intentional conduct and pled in the context of a strict liability claim).

[11] A search of Washington law does not reveal a cause of action for constructive fraud.

speaker's knowledge of its falsity; (5) intent of the speaker that it should be acted upon by the plaintiff; (6) plaintiff's ignorance of its falsity; (7) plaintiff's reliance on the truth of the representation; (8) plaintiff's right to rely upon it; and (9) damages suffered by the plaintiff. *Stiley v. Block*, 130 Wash. 2d 486, 505 (1996). Each element must be established by "clear, cogent and convincing evidence." *Id.* Plaintiff cannot satisfy this burden of proof.

Plaintiff does not identify any particular fraudulent statements made by Ethicon about TVT or the risks or complications associated with TVT. Indeed, she testified under oath that she does not recall Dr. Sleeter showing her any written information about the TVT product before her implant surgery. *MSJ,* ***Ex. 6*** *at 71:21-24*. The only documents that Plaintiff has produced are the records of her healthcare providers. Plaintiff did not produce any literature from Ethicon that she claims to have relied upon or claims was a representation. Plaintiff has presented no evidence that Dr. Sleeter relied upon any alleged fraudulent statements of Ethicon. Plaintiff's claims for common law fraud, fraudulent concealment and constructive fraud should be dismissed.

VIII. BECAUSE CLAIMS FOR PERSONAL INJURY ARE NOT COGNIZABLE UNDER WASHINGTON'S CONSUMER PROTECTION ACT, PLAINTIFF'S CAUSE OF ACTION FOR VIOLATION OF CONSUMER PROTECTION LAWS (COUNT XIII) SHOULD BE DISMISSED.

Under Washington law, "[p]ersonal injury damages [] are not compensable [damages] under the [Washington Consumer Protection Act] and do not constitute injury to business or property." *Ambach v. French*, 167 Wash. 2d 167, 173 (2009) (internal quotations and citations omitted); *see also Ass'n of Wash. Pub. Hosp. Dists. v. Philip Morris Inc.*, 241 F.3d 696, 705 (9th Cir. 2001) ("Expenses for personal injuries are not injuries to business or property under the [Washington Consumer Protection Act]."); *Wash. State Physicians Ins. Exch.*, 122 Wash. 2d at 318 ("Personal injuries are not compensable damages under the [Washington Consumer Protection Act].").

IX. PLAINTIFF DOES NOT SEEK RECOVERY ON A QUASI-CONTRACT THEORY, AND THUS HER UNJUST ENRICHMENT CLAIM (COUNT XV) FAILS AS A MATTER OF LAW.

In Washington, unjust enrichment is based on quasi-contractual obligations and restitution. *Chandler v. Wash. Toll Bridge Auth.*, 17 Wash. 2d 591, 602 (1943). Plaintiff's claim does not sound in contract or quasi-contract, but in tort, and seeks personal injury damages, not a return of the price paid for the TVT. Further, "the WPLA restricts recovery for 'economic loss' to the law of sales," for which privity rules apply. *Wash. Water Power Co.*, 112 Wash. 2d at 851. Plaintiff cannot establish privity. Plaintiff cannot establish a claim for unjust enrichment.

X. PLAINTIFF CANNOT ESTABLISH PRIVITY OR RELIANCE, AND THUS HER CLAIMS FOR BREACH OF EXPRESS WARRANTY (COUNT XI) AND IMPLIED WARRANTY (COUNT XII) SHOULD BE DISMISSED.

As noted, Plaintiff's breach of express and implied warranty claims should be dismissed as duplicative of her failure-to-warn claims. Moreover, her implied warranty claim is "subsumed" within the WPLA. *Lovold v. Fitness Quest Inc.*, No. C11-569Z, 2012 WL 529411, at *5 (W.D. Wash. Feb. 16, 2012); *see* Wash. Rev. Code § 7.72.010(4) ("[under the WPLA,] '[p]roduct liability claim' includes any claim … for … breach of express or implied warranty").

Alternatively, the claims fail on the merits because Plaintiff cannot show privity or reliance. *See* Wash. Rev. Code § 7.72.030(2). Generally, "contractual privity between the buyer and seller must exist before a plaintiff may maintain an action for a breach of warranty," implied or express. *Thongchoom v. Graco Children's Products, Inc.*, 117 Wash. App. 299, 307 (2003). "This requirement is relaxed if the manufacturer makes express representations in advertising, or in some other form, to the plaintiff." *Id.* Still, "[r]ecovery for breach of an express warranty is contingent on a plaintiff's knowledge of the representation." *Id.* (internal quotations and citation omitted); *See also Lovold*, 2012 WL 529411, at *5 (granting summary judgment to defendant where plaintiff failed to present evidence that alleged warranties were the basis of the bargain,

related to a material fact, and were untrue"). Here, Plaintiff does not claim she saw any written information about the product before her surgery which could be a warranty. *MSJ,* ***Ex. 6*** *at 71:21-24.* There is no privity, no direct-to-consumer advertising, and no reliance on any materials, representations or warranties. Plaintiff cannot meet her burden of proof.

Moreover, Plaintiff's express and implied warranty claims fail because they are barred by Washington's statute of limitations. Specifically, RCW 62A.2-725 provides that the action must be commenced within four years after the cause of action has accrued. *Giraud v. Quincy Farm & Chem.*, 102 Wn. App. 443, 451, 6 P.3d 104 (2000) In Washington, "a breach of warranty occurs when tender of delivery is made, except that where a warranty explicitly extends to future performance of the goods and discovery of the breach must await the time of such performance the cause of action accrues when the breach is or should have been discovered." RCW 62A.2-725(2).

Here, Plaintiff purchased the TVT in 2002 when she underwent implant surgery. *MSJ,* ***Ex. 7***. She did not file her warranty claims by April 29, 2006. Plaintiff's breach of express or implied warranty claims must be dismissed based on the statute of limitations.

CONCLUSION

For these reasons, Ethicon's motion for summary judgment should be granted, and Plaintiff's claims should be dismissed with prejudice.

DATED this 6th day of September, 2016.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on September 6, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

s/Jeffrey R. Johnson
Jeffrey R. Johnson